

## 5. 510(k) Summary

k121027

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

**Applicant:** Diamond Diagnostics Inc  
333 Fiske Street  
Holliston MA 01746 DEC 20 2012

**Contact Person:** Kathy Cruz  
Quality Assurance Manager  
Phone: (508) 429-0450 ext. 358  
Fax: (508) 429-0452

**Date Prepared:** 10/25/2012

**Classification Name:** Calibrator, secondary

**Trade Name:** Diamond Diagnostics ATAC 8000/Envoy 500 ISE calibrators

**Device Classification:** 21 CFR 862.1150

**Device Class:** Class II

**Classification Panel:** Clinical Chemistry

**Product Code:** JIT

**Intended Use:** Diamond Diagnostics ATAC 8000/Envoy 500 ISE calibrators are intended to provide calibration points for the Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, and CO<sub>2</sub> electrodes on the ATAC 8000 and Envoy 500 instruments.

**Description of Device:** Diamond Diagnostics ATAC 8000/Envoy 500 ISE Calibrators are intended to serve as a direct replacement to ATAC 8000/Envoy 500 ISE Calibrators.

**Diamond Calibrator Low** consists of an aqueous buffered solution of electrolytes and preservative in De-ionized water. It contains NO human or animal products. It is a liquid packaged in a 22ml screw top amber vial. Each vial contains 20 ml of solution.

**Diamond Calibrator High** consists of an aqueous buffered solution of electrolytes and preservative in De-ionized water. It contains NO human or animal products. It is a liquid packaged in a 22ml screw top amber vial. Each vial contains 20 ml of solution.

Each calibrator is comprised of the following concentrations of analytes,

PN	ISE Calibrator	Na <sup>+</sup> mmol/L	K <sup>+</sup> mmol/L	Cl <sup>-</sup> mmol/L	CO <sub>2</sub> mmol/L
BT-6620943D	Low	92 ± 2.0	3.05 ± 0.05	78 ± 2	11 ± 1
BT-6620944D	High	162 ± 1.0	10.2 ± 0.1	126 ± 1	34.5 ± 1

**Predicate Device:** ATAC 8000 /Envoy 500 ISE Calibrators

**Predicate 510(k) number(s):** K945271

**Comparison with predicate:**

Characteristics	Diamond ATAC 8000/Envoy 500 ISE Calibrators	ATAC 8000 ISE Calibrators
Device	New	Predicate
510(k) Number	K121027	K945271
PN	BT-6620943D ISE Low Calibrator BT-6620944D ISE High Calibrator BT-6620940D (Kit)	347240 ISE Low Calibrator 347240 ISE High Calibrator 347-240 (Kit)
Product Type	Calibrators	same
Intended Use	For <i>in-vitro</i> diagnostics use to provide calibration points for the $\text{Na}^+$ , $\text{K}^+$ , $\text{Cl}^-$ and $\text{CO}_2$ electrodes on the ATAC 8000 instrument having an ISE Module	same
Matrix	Aqueous buffered solution of salts & preservatives in De-ionized water. Contains <u>NO</u> human or animal materials.	same
Packaging, Vial	Glass Vial	Same
Packaging, Product	Box Level, 2x20mL	2x6x20mL
Storage	18-25°C	same
Shelf Life for BT-6620943D	24 months	same
Shelf Life for BT-6620944D	24 months	same

**Stability:**

Accelerated (high temperature) stress test was conducted to support stability claim. Heat stressed reagents showed that calibrator parameters remained within specification thereby demonstrating stability equivalent to ATAC 8000 calibrators.

**Traceability:**

All testing for analytes were conducted using Standards prepared from NIST salts. Testing was also conducted using reference methods.

Analyte	Standard Used for Determination of Analyte Value	Instrument Used
Na, K	NIST 919a, 918a	IL 943 (Flame Photometry)
Cl	NIST 919a	Corning 925, SAT-500 Salt Analyzer, (Titrimetric)
$\text{CO}_2$	NIST 351	Hitachi 912, Olympus-Beckman CX-7

**Expected Values (Controls, Calibrators, or Methods),**

Target values, (or specifications) were obtained by testing reagents analytically prior to bottling, adjusting if necessary to meet specifications, testing analytically during the bottling process and prior to release to stock for distribution.

**Conclusion:**

Based on the results submitted in this pre market notification Diamond ATAC 8000 ISE Calibrators are substantially equivalent to the ATAC 8000 ISE Calibrators in Composition, Intended use, Packaging, and Storage for the measurement of  $\text{Na}^+$ ,  $\text{K}^+$ ,  $\text{Cl}^-$ , and  $\text{CO}_2$ .



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-002

December 20, 2012

Diamond Diagnostics, Inc.  
c/o Kathy Cruz  
333 Fiske Street  
Holliston, MA 01746

Re: k121027

Trade/Device Name: ATAC 8000/Envoy 500 ISE Calibrators  
Regulation Number: 21 CFR 862.1150  
Regulation Name: Calibrator  
Regulatory Class: II  
Product Code: JIT  
Dated: October 25, 2012  
Received: October 26, 2012

Dear Ms. Cruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias  
Director,  
Division of Chemistry and Toxicology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): k121027

Device Name: Diamond Diagnostics ATAC 8000/ Envoy 500 ISE calibrators

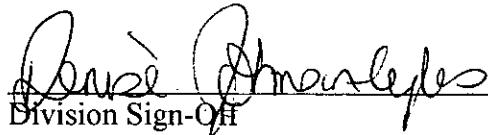
### Indications for Use:

Diamond Diagnostics Calibrators for ATAC 8000 and Envoy 500 instruments are intended to provide calibration points for the  $\text{Na}^+$ ,  $\text{K}^+$ ,  $\text{Cl}^-$  and  $\text{CO}_2$  electrodes on the ATAC 8000 and Envoy 500 instruments.

Prescription Use X And/Or Over the Counter Use \_\_\_\_\_  
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

  
Division Sign-Off  
Office of In Vitro Diagnostics and Radiological Health

510(k) k121027